

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

FERRING PHARMACEUTICALS INC.,
FERRING B.V., and
FERRING INTERNATIONAL CENTER S.A.,

Plaintiffs,

v.

SERENITY PHARMACEUTICALS, LLC, and
REPRISE BIOPHARMACEUTICS, LLC,

Defendants.

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) C.A. No. 1:17-cv-09922 (RWS)

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) ECF Case

SERENITY PHARMACEUTICALS, LLC,
REPRISE BIOPHARMACEUTICS, LLC, and
AVADEL SPECIALTY
PHARMACEUTICALS, LLC,

Counterclaim-Plaintiffs,

v.

FERRING B.V., FERRING INTERNATIONAL
CENTER S.A., and FERRING
PHARMACEUTICALS INC.,

Counterclaim-Defendants.

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) C.A. No. 1:17-cv-09922 (RWS)

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) ECF Case

**FERRING’S OPENING BRIEF IN SUPPORT OF MOTION FOR LEAVE TO FILE
(1) SECOND AMENDED COMPLAINT FOR DECLARATORY JUDGMENT AND
(2) REPLY TO COUNTERCLAIMS AND AFFIRMATIVE DEFENSES, AND
AMENDED COUNTERCLAIMS IN REPLY**

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I. INTRODUCTION

Ferring¹ submits this opening brief in support of its motion for leave to file (1) a Second Amended Complaint for Declaratory Judgment (“Second Amended Complaint”) and (2) a Reply to Counterclaims and Affirmative Defenses, and Amended Counterclaims in Reply (“Amended Counterclaims”) before the deadline for amending pleadings in the scheduling order (D.I. 131 at 5).² Ferring’s Second Amended Complaint and Amended Counterclaims add an additional allegation of inequitable conduct of U.S. Patent Nos. 7,405,203 (“the ’203 patent”), 7,579,321 (“the ’321 patent”), and 7,799,761 (“the ’761 patent”) (collectively, “patents in suit”).

Inequitable conduct in patent cases is results in the patents in suit should being held unenforceable because the patent applicant deceived the U.S. Patent and Trademark Office (“PTO”) when obtaining the patents in suit. Ferring alleged inequitable conduct in its original Complaint and its first Amended Complaint for Declaratory Judgment (“First Amended Complaint”) and detailed specific instances of inequitable conduct that it understood from the available record. Ferring now seeks leave to amend its First Amended Complaint and Counterclaims in Reply to add additional allegations and grounds supporting its unenforceability claims.

The newly-pled allegations add additional examples to Ferring’s inequitable conduct allegations. Because allegations of inequitable conduct require pleading with particularity, Ferring rightfully waited to plead the additional grounds for its inequitable conduct claims until after it had more fully developed the underlying facts. The amendments are proposed before

¹ “Ferring” refers to plaintiffs/counterclaim-defendants Ferring Pharmaceuticals Inc., Ferring B.V., and Ferring International Center S.A.

² The patents in suit share a common specification. For ease of reference, citations to the common specification are to the ’203 patent only. Corresponding citations can be found in the ’321 patent and ’761 patent.

depositions have been completed, before the close of fact discovery, and before the deadline for amending pleadings in the scheduling order (D.I. 131 at 5), and were not unduly delayed.

Moreover, the amendments will not cause undue prejudice to Counterclaimants.³ The new allegations require no fact discovery from Ferring. The additional allegations are based on facts already known to Counterclaimants and do not add new parties. Finally, the allegations are not futile. Taken as true, the additional grounds prove inequitable conduct in the procurement of the patents in suit. Pursuant to Rule 15(a), in circumstances such as these, leave to amend should be “freely given.” Ferring therefore respectfully requests that the Court grant its motion for leave to file its proposed Second Amended Complaint (attached as Exhibit 1 (clean) and Exhibit 2 (red-lined)) and Amended Counterclaims (attached as Exhibit 3 (clean) and Exhibit 4 (red-lined)).

II. FACTUAL BACKGROUND

The Scheduling Order in this case sets a deadline of October 1, 2018 for amending the pleadings. (D.I. 131 at 5.)

In its First Amended Complaint, Ferring sought a declaratory judgment of unenforceability due to inequitable conduct during the prosecution of the patents in suit. As required under the particularized pleading standard for inequitable conduct claims, Ferring supported its inequitable conduct count with extensive factual allegations setting forth “the who, what, when, where, and how of the material misrepresentation or omission committed before the PTO.” *Lumos Tech. Co. v. JEDMED Instrument Co.*, No. 16CV6939(DLC), 2017 WL 1322213, at *1 (S.D.N.Y. Apr. 10, 2017, *quoting Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009)). The First Amended Complaint specifically alleged, *inter alia*, that at the times Dr. Fein signed and submitted his Combined Declaration, “he knew that (i) he was not the

³ “Counterclaimants” refers to defendant/counterclaimant Serenity Pharmaceuticals, LLC (“Serenity”), defendant/counterclaimant Reprise Biopharmaceutics, LLC (“Reprise”), and counterclaimant Avadel Specialty Pharmaceuticals, LLC.

sole inventor of the subject matter claimed in the Patents in Suit, (ii) his claim of priority for the subject matter claimed in the Patents in Suit was false, and (iii) his claim to sole inventorship of the subject matter claimed in the Patents in Suit was disputed by Ferring.” (D.I. 18 ¶ 143.)

Ferring also asserted in its First Amended Complaint other counts directed to the patents in suit. Moreover, in its Reply to Counterclaims and Affirmative Defenses, and Counterclaims in Reply (D.I. 115; “Ferring’s Reply”), Ferring asserted affirmative defenses against allegations of infringement of claims of the ’203 patent and the ’321 patent, including allegations of non-infringement.

III. LEGAL STANDARD

Leave to amend one’s pleadings “shall be freely given when justice so requires.” Fed. R. Civ. P. 15(a); *United States ex rel. Maritime Admin. v. Continental Ill. Nat’l Bank & Trust Co. of Chi.*, 889 F.2d 1248, 1254 (2d Cir. 1989) (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)); *Pangburn v. Culbertson*, 200 F.3d 65, 70 (2d Cir. 1999). The Supreme Court has made clear that:

In the absence of any apparent or declared reason—such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of the amendment, etc.—the leave sought should, as the rules require, be “freely given.”

Foman, 371 U.S. at 182, *quoted in TouchTunes Music Corp. v. Rowe Int’l Corp.*, 847 F. Supp. 2d 606, 621 (S.D.N.Y. 2012) (Sweet, J.) (granting motion to amend pleadings to add inequitable conduct defense). “Mere delay is not, of itself, sufficient to justify denial of a Rule 15(a) motion.” *TouchTunes*, 847 F. Supp. 2d at 621 (internal quotation and citation omitted). Where a proposed amendment is not futile, a party should be afforded the opportunity to test the claim on its merits. *See id.* at 624 (quoting *Nycomed U.S. Inc. v. Glenmark Generics Ltd.*, No. 08-cv-5023, 2010 WL 1257803, at *18 (E.D.N.Y. March 26, 2010)); *Nerney v. Valente & Sons Repair*

Shop, 66 F.3d 25, 28 (2d Cir. 1995); *United States ex rel. Maritime Admin*, 889 F.2d at 1254. An amendment is futile if it “would not be able to withstand a dispositive pretrial motion.”

TouchTunes, 847 F. Supp. 2d at 621. Further, “[a]s courts in this circuit have repeatedly held, ‘[t]he party opposing an amendment has the burden of establishing that leave to amend would be prejudicial or futile.’” *Nycomed*, 2010 WL 1257803, at *13 & n.19 (citations omitted); *see also id.* at 12. Accordingly, in a case such as this one, “amendment should normally be permitted.” *Nerney*, 66 F.3d at 28 (citing *Foman*, 371 U.S. at 182).

IV. ARGUMENT

A. Ferring’s Amendments Should Be Allowed Because They Are Made in Good Faith and Without Undue Delay

Ferring’s First Amended Complaint and Counterclaims in Reply already contain well-pled inequitable conduct defenses for the patents in suit based on the purported inventor Seymour Fein’s representations to the PTO regarding the inventorship of the patents in suit. Ferring has developed additional grounds supporting its claims of inequitable conduct allegations. “Parties ‘have been permitted to amend their pleadings to assert new claims long after they acquired the facts necessary to support those claims.’” *ResQNet.com, Inc. v. Lansa, Inc.*, 382 F. Supp. 2d 424, 450 (S.D.N.Y. 2005) (Sweet, J.) (quoting *Richardson Greenshields Secs., Inc. v. Lau*, 825 F.2d 647, 653 n. 6 (2d Cir.1987) (collecting cases)) (noting that the three year interval between the amended answer and motion for leave to further amend is within the norm for cases where amendments have been allowed), *reversed-in-part and vacated-in-part on other grounds by* 594 F.3d 860 (Fed. Cir. 2010).

Ferring’s new allegations are not unduly delayed. Importantly, these additional allegations are being filed before the deadline for amending pleadings in this case. Courts have regularly recognized that waiting to obtain further evidence “reflect[s] prudence rather than

undue delay.” *Stratagem Dev. Corp. v. Heron Int’l N.V.*, No. 90 CIV. 6328 (SWK), 1992 WL 276844, at *2 (S.D.N.Y. Sept. 30, 1992). This is a particularly appropriate course for a party contemplating inequitable conduct allegations. *See, e.g., ResQNet.com*, 382 F. Supp. 2d at 448. Ferring sought the present amendments only after investigating facts that provided additional support for its inequitable conduct claims. Having determined that there are sufficient legal and factual bases for the added allegations, Ferring timely moves to add them to ensure a thorough, clear, and specific presentation of the grounds for inequitable conduct. Ferring’s amendments should be allowed.

B. Counterclaimants Will Not Be Prejudiced by Ferring’s Amendments, and the Proposed Amendments Are Not Futile

A proposed amendment results in undue prejudice if a new claim would “(i) require the opponent to expend significant additional resources to conduct discovery and prepare for trial; (ii) significantly delay the resolution of the dispute; or (iii) prevent the plaintiff from bringing a timely action in another jurisdiction.” *ResQNet.com*, 382 F. Supp. 2d at 449 (quoting *Monahan v. New York City Dep’t of Corrections*, 214 F.3d 275, 284 (2d Cir. 2000)). “‘The type of prejudice that warrants denial of leave to amend is usually such that it puts [the opposing party] at an unfair disadvantage,’ such as the addition of a new claim on the eve of trial.” *Nycomed*, 2010 WL 1257803, at *12 (citation omitted).

None of these prejudicial concerns are present here. First, the conduct that is the subject of the inequitable conduct allegations was committed by Fein—a founder and a principal of two of the Counterclaimants. For both amendments, Counterclaimants will not be required to expend any additional resources. Second, Counterclaimants have long been on notice of the inequitable conduct claims and the amendments add no new parties, only more detailed allegations supporting Ferring’s existing inequitable conduct count. Third, these amendments are being filed

before the October 1, 2018 deadline for amending pleadings in this case. (D.I. 131 at 5.) Thus, each of the “prejudice” factors demonstrates that Counterclaimants will not be prejudiced by the additional allegations and grounds regarding Ferring’s inequitable conduct claims.

The proposed amendments are not futile. Counterclaimants bear the burden of establishing futility and cannot meet that burden. An amendment is futile if it “would not be able to withstand a dispositive pretrial motion.” *TouchTunes*, 847 F. Supp. 2d at 621.

In addition, with respect to the inequitable conduct allegation, to prevail “the accused infringer must prove that the applicant misrepresented or omitted material information with the specific intent to deceive the PTO.” *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011) (en banc); *see also eSpeed, Inc. v. BrokerTec USA, L.L.C.*, 480 F.3d 1129, 1135 (Fed. Cir. 2007); *Nycomed*, 2010 WL 1257803, at *13 & n.19. When a patentee has engaged in affirmative acts of egregious misconduct, however, the misconduct is material. *Therasense*, 649 F.3d at 1292. Examples of affirmatively egregious misconduct are found in the new allegation of inequitable conduct in Ferring’s Second Amended Complaint and Ferring’s First Amended Counterclaims in Reply. The decision in *Therasense* also confirms that intent to deceive the PTO may be shown by direct evidence, or it may be inferred from indirect and circumstantial evidence if it is the single most reasonable inference able to be drawn from the evidence. *Therasense*, 649 F.3d at 1290.

While inequitable conduct must be pled with particularity under Rule 9(b), *TouchTunes*, 847 F. Supp. 2d at 622, “at this stage, ‘the issue before the Court is not whether [Ferring] will ultimately prevail, but whether it is entitled to offer evidence’ to support its allegations of inequitable conduct.” *Id.* at 624 (alterations omitted), *quoting Nycomed*, 2010 WL 1257803, at *18. Nevertheless, Ferring’s Second Amended Complaint and First Amended Counterclaims in

Reply allege “sufficient facts to nudge its claims ‘across the line from conceivable to plausible.’”

Id. The proposed Seconded Amended Complaint and First Amended Counterclaims in Reply set out Ferring’s additional inequitable conduct allegations in the detail required by Rule 9(b) and *Therasense*. In particular, the allegations set out “the who, what, when, where, and how” of Fein’s inequitable conduct as it relates to Example 8. (*See, e.g.*, Exs. 1 and 2 at ¶¶ 142-56; Exs. 3 and 4 at Counterclaims ¶¶ 42-56.)

V. CONCLUSION

For the foregoing reasons, Ferring respectfully request the Court grant in its entirety Ferring’s motion for leave to file (1) a Second Amended Complaint and (2) a Reply to Counterclaims and Affirmative Defenses, and Amended Counterclaims in Reply.

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